ENVIRONMENTAL TESTING LABORATORY CERTIFICATION BULLETIN

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Personnel Requirements

The Technical Director is considered the responsible individual from the perspective of the ELCP. The title each laboratory gives the individual is not critical, but someone must take on the responsibilities for the entire laboratory technical operation with the option of having multiple staff covering appropriate fields of accreditation. The technical director or a specific technical director's name will appear as the contact person for all certification activities and be included on the published database.

The Technical Director exercises actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results. This person's duties shall include, but not be limited to, monitoring standards of performance in quality control and quality assurance; monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data.

The technical director(s) who is absent for a period of time exceeding 15 consecutive calendar days shall designate another full-time staff member meeting the qualifications of the technical director(s) to temporarily perform this function. If this absence exceeds 65 consecutive calendar days, the ELCP shall be notified in writing

Technical Director Requirements by Type of Testing Performed

Type of testing	Minimum Qualifications
Chemical analysis	A full time employee with a bachelors degree in the chemical, environmental, biological sciences, physical sciences or engineering, with at least 24 college semester credit hours in chemistry and at least two years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory seeks or maintains accreditation. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience
Limited to inorganic chemical analysis [other than metals]	A full time employee with an earned associate's degree in the chemical, physical or environmental sciences, or two years of equivalent and successful college education, with a minimum of 16 college semester credit hours in chemistry. In addition, such a person shall have at least two years of experience performing such analysis.

Type of testing	Minimum Qualifications
Microbiological or Biological analysis	A full time employee with a bachelors degree in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering with a minimum of 16 college semester credit hours in general microbiology and biology and at least two years of experience in the environmental analysis of representative analytes for which the laboratory seeks or maintains accreditation. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience.
Microbiological limited to fecal coliform, total coliform and standard plate count	A full time employee with an associate's degree in an appropriate field of the sciences or applied sciences, with a minimum of four college semester credit hours in general microbiology. Two years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree. In addition, each person shall have one year of experience in environmental analysis.
Radiological analysis	A full time employee with a bachelor’s degree in chemistry, physics or engineering with 24 college semester credit hours of chemistry with two or more years of experience in the radiological analysis of environmental samples. A masters or doctoral degree in one of the above disciplines may be substituted for one year experience.
Microscopic examination of asbestos or airborne fibers	
TEM	A full time employee with a bachelor's degree, successful completion of courses in the use of the instrument, and one year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.
Polarized Light Microscopy	A full time employee with an associate's degree or two years of college study, successful completion of formal coursework in polarized light microscopy, and one year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.
Phase Contrast Microscopy	A full time employee with an associate's degree or two years of college study, documentation of successful completion of formal coursework in phase contrast microscopy, and one year of experience, under supervision, in the use of the instrument.

Exceptions to Technical Director Requirements

Situation	Minimum Qualification
drinking water or sewage treatment facility	a full-time employee of a sewage treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational and experience requirements serving as the director of the accredited laboratory devoted exclusively to the examination of environmental samples taken within such facility system. Such accreditation for a water treatment facility and/or a sewage treatment facility shall be limited to the scope of that facility's regulatory permit, and when the facility's laboratory is analyzing water treatment/sewage treatment samples collected within the state where the laboratory is situated…
industrial waste treatment facility	A full-time employee with a minimum of one year of experience under supervision in environmental analysis shall be deemed to meet the requirements for serving as the director of an accredited laboratory devoted exclusively to the examination of environmental samples taken within such facility for the scope of that facility's regulatory permit. Such accreditation for a industrial waste treatment facility shall be limited to laboratories analyzing industrial waste treatment samples collected within the state where the laboratory is situated…

Quality Assurance Officer qualifications are much shorter. The individual function as a QA officer in a certified laboratory must have documented training and/or experience in QA/QC procedures and be knowledgeable in the quality system as defined under NELAC. They must also have a general knowledge of the analytical test methods for which data review is performed. General knowledge is difficult to define but experience running the method is adequate. Less obvious would be classes teaching the technology. The bottom line is looking for outcomes and if the Quality System is functioning well the QAO is qualified. When the quality system isn't working then the qualifications are analyzed much closer.

Grandfathering

Individuals who do not meet the educational requirements but possess the required experience may qualify as technical director(s) if following conditions are met:
a) The person must have been a technical director of record for the laboratory on the date the rule incorporating the NELAC standard was effective and must have been a technical director in that laboratory continuously for the previous 12 months or more.
b) The person will be approved as a technical director for only those fields of accreditation for which they have been technical director in that laboratory for the previous 12 months or more.
c) A person who is admitted as a technical director under these conditions, and leaves the laboratory, may be admitted as technical director for the same fields of accreditation in another certified laboratory.

Ethics or Data Integrity

The quality manual for the laboratory is the document describing how things are done in the laboratory. The QA manual is the yardstick the laboratory is measured against for certification. In each QA manual there must be a number of specific items addressed, one of which deals with ethics in the laboratory.

The standard says: **5.5.2 Quality Manual [NELAP 2001]** *The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of this Standard.*

….

The quality manual and related quality documentation shall also contain:
….
u) ethics policy statement developed by the laboratory and processes/procedures for educating and training personnel in their ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions;

The standard itself gives little detail of what specifics must be included, however, each item listed must be addressed.
Proposed language for future standards may provide greater detail.

More specifics and examples of how to accomplish what the policy statement describes are found under the responsibilities of management. The standard says: **5.6.2 Laboratory Management Responsibilities [NELAP 2001]** *In addition to 5.4.2.d, the laboratory management shall be responsible for:*
….
c) Ensuring that the training of each member of the technical staff is kept up-to-date (on-going) by the following:
….
3) Training courses in ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions. Evidence must also be on file which demonstrates that each employee has read, acknowledged and understood their personal ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions.
….
h) Developing a proactive program for prevention and detection of improper, unethical or illegal actions. Components of this program could include: internal proficiency testing (single and double blind); post-analysis, electronic data and magnetic tape audits; effective reward program to improve employee vigilance and co-monitoring; and separate SOPs identifying appropriate and inappropriate laboratory and instrument manipulation practices.

It is important to note that this requirement is evolving and the current standard provides a minimum for the laboratories to meet. Future standards have more specific clarifying language.

Quality System 5.4.2.6 [NELAP 2002] Covers both citations in the 2001 standard with:
5.4.2.*6* *The laboratory shall establish and maintain data integrity procedures. These procedures shall be defined in detail within the quality manual. There are four required elements within a data integrity system. These are 1) data Integrity training, 2) signed data integrity documentation for all laboratory employees, 3) in-depth, periodic monitoring of data integrity, and 4) data integrity procedure documentation. The data integrity procedures shall be signed and dated by senior management. These procedures and the associated implementation records shall be properly maintained and made available for assessor review. The data integrity procedures shall be annually reviewed and updated by management.*
5.4.2.6.*1* *Laboratory management shall provide a mechanism for confidential reporting of data integrity issues in their laboratory. A primary element of the mechanism is to assure confidentiality and a receptive environment in which all employees may privately discuss ethical issues or report items of ethical concern.*
5.4.2.6.2 *In instances of ethical concern, the mechanism shall include a process whereby Laboratory management are to be informed of the need for any further detailed investigation.*

Matrix versus Program

You will begin to see a transition on your certificate letters that indicate a matrix. You will see Potable water, Non-potable water, and Solid And Chemical Waste. As the NELAC standards move to fields of accreditation defined as matrix-technology/method-analyte/analyte group [NELAC 2001] we will take the first step by showing the equivalence of the program to the matrix. SDWA is equivalent to potable water and etc.

Six Month Rule for PT

The April 2002 edition of *ENVIRONMENTAL TESTING LABORATORY CERTIFICATION BULLETIN* contained an article about PT requirements for initial and on going certification based on PT. Since this interpretation of

the standard was not well understood at the time by all laboratories the ELCP chose not to immediately enforced the six month requirement. Instead, the ELCP gave the laboratories a number of months to get on an acceptable schedule that will avoid having a PT failure based on non-participation.

Review of the April 2002 article:

What is approximately six months?

The NELAC standard at 2.7.2 Initial or Continuing PT Studies is written as follows:
A laboratory seeking to obtain or maintain accreditation shall successfully complete two initial or continuing PT studies for each requested field of proficiency testing within the most recent three rounds attempted. For a laboratory seeking to obtain accreditation, the most recent three rounds attempted shall have occurred within 18 months of the laboratory's application date. Successful performance is described in Appendix C. When a laboratory has been granted accreditation status, it shall continue to complete PT studies for each field of proficiency testing and maintain a history of at least two acceptable PT studies for each field of proficiency testing out of the most recent three. For initial accreditation, the laboratory must successfully analyze two sets of PT studies, the analyses to be performed at least 15 calendar days apart from the closing date of one study to the shipment date of another study for the same field of proficiency testing. For continuing accreditation, completion dates of successive proficiency rounds for a given field of proficiency testing shall be approximately six months apart. Failure to meet the semiannual schedule is regarded as a failed study. Initial or continuing PT Studies must meet all applicable criteria described in this chapter and associated appendices.

This section of the standard has a great deal of information. Probably the least straightforward part of it is the reference to keeping PT studies in the suggested time frames, specifically approximately six months apart. To make this an auditable time period the ELCP has adopted and interpretation that approximately six months means no more than 7 months from the closing date of one study to the closing date of the subsequent study.

Now, with all of that said the requirement for the level of participation found in the NELAC Standard at **2.4.1 Required Level of Participation** requires that: *Each laboratory shall participate in at least two PT studies for each field of proficiency testing per year….*

It is important to remember that PT is evaluated by analyte [field of proficiency testing] which means studies for each analyte must be no more than 7 months apart [closing date to closing date]. Make up studies, done as soon as 15 days after the closing date of the previous study, "start the clock" for the analytes in the makeup study. In essence you can do a study every 15 days but they must be done at least two times each year and within 7 months of the last closing date.

When PT studies do not meet these criteria [at least two times each year and within 7 months] it counts as if the study was not done and all analytes fail. This failure is counted into the "two of three" grading structure and can have dire consequences on a laboratories certification status for the effected analytes.

The ELCP will start in January 2003 to look back each time a PT study is received to determine if the laboratory is in compliance. We will look back 14 months to see if 2 of the last 3 PT studies have passing scores for each approved analyte.